

# The Facial Function in Unilateral Craniofacial Microsomia

Published: 14-10-2013

Last updated: 22-04-2024

The main objective is to evaluate the facial function in patients with UCM. In this study we set out to evaluate how the facial deformity influences the self-esteem and self-evaluation i.e. satisfaction of the patients and what the valence is of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38550

### Source

ToetsingOnline

### Brief title

Facial function in UCM

### Condition

- Other condition

### Synonym

hemifacial microsomia, underdevelopment of a half of a face

### Health condition

Craniofaciale afwijkingen

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Hemifacial microsomia, Psychology, Self evaluation, Unilateral craniofacial microsomia

## Outcome measures

### Primary outcome

The outcome of the CBSA, CBSK or CBSJV questionnaires will be processed in the correlating scales: CBSA-scale, CBSK-scale or CBSJV-scale. The outcome of the Mijn gezicht en lichaam questionnaire will be processed in specific 5point scales

### Secondary outcome

n.a.

## Study description

### Background summary

Unilateral craniofacial microsomia (UCM) is a congenital deformity in which patients have a hemilateral underdevelopment of the face. Structures involved are i.a. the mandible, auricle, zygoma, eyes and facial nerve. Reported incidences lie from 1:3500 to 1:20000. The variance in incidence number may be due to the variance in presentation. In some patients the deformity is rarely visible, others are in need of several corrective surgeries. Although a lot has been written on the technical aspects of the surgery and its (long) term outcomes, the subjective function of the face in terms of self-esteem and self-evaluation is an under exposed aspect of the abnormality.

### Study objective

The main objective is to evaluate the facial function in patients with UCM. In this study we set out to evaluate how the facial deformity influences the

self-esteem and self-evaluation i.e. satisfaction of the patients and what the valence is of these parameters.

### **Study design**

The study is mostly a cross-sectional explorative study. However, patients who will undergo surgery to correct the deformity will be asked to fill out the questionnaires twice: pre and post surgery. An estimated 4-10 patients will be included in the latter group.

### **Study burden and risks**

The risk and burden of this study is marginal.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230  
Rotterdam 3015CE  
NL

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230  
Rotterdam 3015CE  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)

Adults (18-64 years)  
Children (2-11 years)  
Elderly (65 years and older)

## Inclusion criteria

The study population consists of all patients with unilateral craniofacial microsomia presented at the Erasmus University Medical Centre/Sophia Children's hospital

## Exclusion criteria

Not capable of reading and understanding the dutch language, analphabetic, mental retardation.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-07-2014
Enrollment:	160
Type:	Actual

## Ethics review

Approved WMO

Date:	14-10-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL44880.078.13